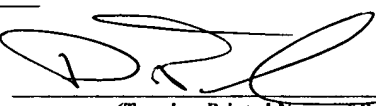

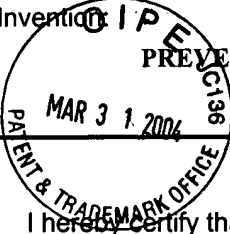
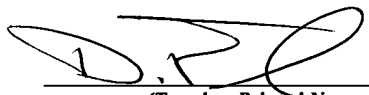
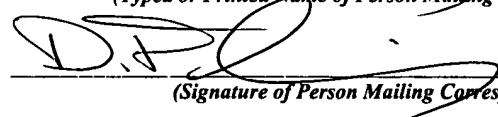
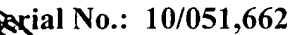


<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b> Applicant(s):			Docket No. <b>31140B</b>
Serial No. <b>10/051,662</b>	Filing Date <b>January 18, 2002</b>	Examiner <b>R. Cook</b>	Group Art Unit <b>1614</b>
Invention: <b>PREVENTION OF OVARIAN CANCER BY ADMINISTRATION OF A VITAMIN D COMPOUND</b>			
I hereby certify that the following correspondence: <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"><b>1449 Form (with listed references)</b></div> <p style="text-align: center;"><i>(Identify type of correspondence)</i></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"><div style="text-align: center;"><u><b>March 31, 2004</b></u> <i>(Date)</i></div><div style="text-align: center;"> <hr/><i>(Typed or Printed Name of Person Mailing Correspondence)</i>  <hr/><i>(Signature of Person Mailing Correspondence)</i> <div style="margin-top: 10px;"><b>EL395644806US</b> <hr/><i>("Express Mail" Mailing Label Number)</i></div></div></div> <div style="text-align: center; margin-top: 20px;"><b>Note: Each paper must have its own certificate of mailing.</b></div>			

<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b> Applicant(s):			Docket No. <b>31140B</b>
Serial No. <b>10/051,662</b>	Filing Date <b>January 18, 2002</b>	Examiner <b>R. Cook</b>	Group Art Unit <b>1614</b>
Invention: <b>PREVENTION OF OVARIAN CANCER BY ADMINISTRATION OF A VITAMIN D COMPOUND</b>			
			
I hereby certify that the following correspondence: <div style="border: 1px solid black; height: 50px; margin-top: 10px;"><b>Supplemental Information Disclosure Statement</b></div> <p style="text-align: center;"><i>(Identify type of correspondence)</i></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <div style="display: flex; justify-content: space-between; align-items: flex-end; margin-top: 20px;"><div style="text-align: center;"><u>March 31, 2004</u> <i>(Date)</i></div><div style="text-align: center;"> _____ <i>(Typed or Printed Name of Person Mailing Correspondence)</i>  _____ <i>(Signature of Person Mailing Correspondence)</i> <b>EL395644806US</b> _____ <i>("Express Mail" Mailing Label Number)</i></div></div>			
<b>Note: Each paper must have its own certificate of mailing.</b>			



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: Prevention of Ovarian Cancer by  
Administration of a Vitamin D Compound

Group Art Unit: 1614

## 01 FC:1806 180.00 DA

A. The Neer Patent

The International Preliminary Examination Report for Applicants' PCT application PCT/US98/11737 cites the Neer patent. A copy of the Report is included herewith. The report identifies col. 7, lines 16-19 as pertinent to one claim in the PCT application. The cited portion of the Neer patent reads:

A typical pharmaceutical mixed composition of the invention would contain PTHF in combination with a hydroxylated vitamin D compound or calcium in a form suitable for use as a dietary calcium supplement.

The Neer patent was cited only against claim 25 in the pending PCT application. The other claims were found to have novelty and inventive step over the references cited. (*See International Preliminary Examination Report, V.1.*).

Claim 25 of application PCT/US98/11737 reads as follows:

25. A pharmaceutical composition for inhibiting the conversion of non-neoplastic ovarian epithelial cells to neoplastic cells comprising a *Vitamin D compound* and a *hormone product*.

(*See PCT/US98/11737 submitted herewith*). Thus, claim 25 was directed to a combination of a Vitamin D compound and a hormone product. The International examining entity cited the Neer reference as showing that claim 25 lacked novelty. (*See International Preliminary Examination Report at V.1.*). Neer combines a parathyroid hormone, PTHF, with either Vitamin D or calcium.

However, the International Application also included claims directed to the combination of Vitamin D and a progestin product, specifically claims 26-34. Claim 26 is exemplary:

26. The pharmaceutical composition of claim 25 wherein said hormone is a *progestin product*.

With respect to the claims directed to the combination of Vitamin D and a progestin product, the International examining entity found both novelty and inventive step. (See International Preliminary Examination Report at V.1.). Neer does not disclose or suggest any use of a progestin product.

In the pending U.S. Application Serial No. 10/051,662 at issue here, claims 35 and 45 were the only two claims that broadly recited “a hormone product.” However, those claims are now amended to be more narrowly drawn to “a progestin product.”

The Supplemental Information Disclosure Statement also includes the Initial International Search Report in connection with the same application PCT/US98/11737.

**B. The Full Need Reference**

In the August 7, 2003 Office Action, the Examiner brought to the Applicants’ attention the abstract of the Need et al. reference. Applicants submitted a copy of the full Need reference with their prior amendment of February 9, 2004. As explained in the Applicants’ amendment filed February 9, 2004, the Need reference does not teach or provide any motivation to make: (1) a single unit dosage of Vitamin D and progestin; (2) a contraceptively effective regimen having both Vitamin D and a progestin; or (3) any dosages for administration to post-menopausal women in specific dosages different from what Need used.

Please charge the fee required by 37 CFR §1.97(c)(2) and §1.17(p), and any additional fees, to Deposit Account No. 18-1942.

Respectfully submitted,



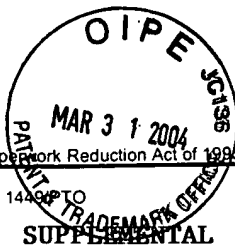
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Raymond N. Nimrod  
ROPER & QUIGG  
Reg. No. 31,987  
200 South Michigan Avenue  
Suite 1000  
Chicago, Illinois 60604  
Tel (312) 408-0855

March 31, 2004



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PTO/SB/08B (08-03)

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SUPPLEMENTAL

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/051,662
Filing Date	01/18/02
First Named Inventor	RODRIGUEZ
Art Unit	1614
Examiner Name	R. Cook
Attorney Docket Number	31140B

Sheet 2 of 2

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	F1	Need et al., "Comparison of calcium, calcitrol, ovarian hormones and nandrolone in the treatment of osteoporosis." Maturitas 8:275-280 (1986).	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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